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GIHF AI

German Israeli Health Forum for Artificial Intelligence

Policy Briefing "Regulation"

New digitalisation strategy in Germany and current draft law in Israel

Building on the first policy briefing of the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) on regulation for innovation-enabling use of health data in the European and Israeli context, this briefing highlights recent regulatory developments in Germany and Israel. Adv. Tamar Tavory, Special Counsel at Arnon, Tadmor-Levy, addresses the Israeli Ministry of Health's current Draft Medical Information Portability Law in her guest contribution. This is contrasted with the main contents of the Digitalisation Strategy for Health and Care presented by the BMG at the beginning of March, with a focus on the topic of healthcare data use.

"**Germany's healthcare system is decades behind in digitalization. We can no longer justify this**. That's why we're making a fresh start - opening up electronic patient records for everyone, making electronic prescriptions suitable for everyday use, and facilitating research based on health data. **Modern medicine is based on digitalization and data**. Harnessing their benefits makes treatment better."[1], said Federal Minister of Health Professor Karl Lauterbach at the Federal Press Conference as part of the presentation of the Digitalisation Strategy for Health and Care in March 2023.

Especially with regard to the application of AI in healthcare, the question of data use for care and research is of great importance and is also reflected in the Regulation for a European Health Data Space (EHDS) and the European AI Regulation (EU AI Act), which will be discussed extensively in the context of the GIHF-AI.[2] In the following, the aspects of the digitalization strategy with regard to legislation on the use of healthcare data will be discussed. It also looks at the current legislative situation in Israel, which is decades ahead of Germany in terms of digitalization of healthcare[3], as highlighted in the publication by ELNET on "Digitization and Innovation in German and Israeli healthcare: An inventory".[4]

The Digitalisation Strategy for Health and Care

Among other things, the digitalisation strategy addresses the question of how care processes, data use and technologies must evolve by the end of the decade in order to improve healthcare. **Two legislative projects that will make a key contribution in this context are the planned Digital Act and the Health Data Use Act.**

The Digital Act

As part of the Digital Act, the **electronic patient record (ePA) is to be introduced for all statutorily insured persons by the end of 2024**, with an opt-out option. At the same time, the **e-prescription is to become the mandatory standard in pharmaceutical care from January 1, 2024,** and its use is to be simplified. The e-prescription can then be redeemed using both the health card and the e-prescrip-

tion app or an ePA app. It is also possible to redeem by paper printout. An automated digital medication overview in the ePA, closely linked to the e-prescription, is intended to prevent unwanted drug interactions.

In addition, the **Gesellschaft für Telematik (gematik GmbH) is to be further developed into a digital agency wholly owned by the federal government** and its ability to act strengthened. Furthermore, it is planned to enable assisted telemedicine in pharmacies or health kiosks, which will lead to noticeable added value, especially in underserved regions. **Structured treatment programs (disease management programs - DMPs) are to be supplemented by more digitized programs**.

Also, an **interdisciplinary committee** consisting of representatives of the Federal Commissioner for Data Protection and Freedom of Information (BfDI), the Federal Office for Information Security (BSI), medicine and ethics will **advise the Digital Agency on its decisions and make recommendations on issues of data protection, data security, data use and user-friendliness**. This committee replaces the previous agreement process with BSI and BfDI.[5]

The Health Data Use Act (GDNG)

The Health Data Use Act (GDNG) requires that a **central data access and coordination point be established** to facilitate access to research data from a variety of sources, such as data from registries and health insurance data.

The **event-related linking of different data sources is to be made possible via research indicators, starting here with data from the Health Data Hub (FDZ) and the national cancer registries**. The regulation on lead data protection supervision for cross-state research projects will be further developed and expanded to include all health data in a clearer form.
The **Health Data Hub (FDZ) at the Federal Institute for Drugs and Medical Devices (BfArM) is to be further developed** in order to also be able to process requests for data access from the researching industry. The purpose of use, not the sender, is to be the decisive factor in approving requests.

The **release of data from the electronic patient record (ePA) is to be developed into an opt-out**. Pseudonymized ePA data will thus be usable for research purposes via the FDZ in the future, provided that insured persons do not object to this. A **data cockpit will be established in the ePA** for simple and user-friendly objection.[6]

Cooperation with Israel in the field of research and health

According to the Israel Survey 2023 published by ELNET, **European parliamentarians are calling for closer cooperation with Israel in the area of research and health**.[7] In order to implement this and understand the current status quo in terms of health data use in Israel, the following section will look at Israel's legislation in general, with a focus on the newly published draft Medical Information Portability Law.

Access to medical data in Israel and the legal aspects

Guest article by Adv. Tamar Tavory, Special Counsel, Arnon, Tadmor-Levy

In the era of digital health data, the possibility to access and share medical data is crucial for patients, health care providers, and for medical research and innovation in healthcare.

Israeli Healthcare System – Background

According to the National Health Insurance Law, **every Israeli resident is entitled to membership in one of the four Israeli HMOs** and to receive, without charge, healthcare services included in the national "health basket", which is updated yearly. Most Israelis are also registered in supplementary health plans provided by the HMOs under MOH supervision, and some are insured, as well, by private insurance policies. Many hospitals in Israel are

owned by the Israeli government; some hospitals are owned by Clalit, the largest HMO; other hospitals are owned by Assuta, a subsidiary of Maccabi, a large HMO; and some hospitals and medical centers are privately owned. **Israel's hospitals and HMOs initiate and encourage innovation, in part by leveraging their access to high-quality digital medical data**.

Medical Data – Israeli Legislation

The **patient's right to privacy is a constitutional right according to the Basic Law**: Human Dignity and Liberty, and the right to privacy in medical data is protected by the Privacy Protection Law and the Patient's Rights Act. Subject to certain exceptions, **medical data may be used only for the purpose for which they are provided by the data subject**. **Additional uses, including secondary use of medical data, are generally subject to data subject consent**. In addition, **secondary use of medical data, cloud computing of medical data and the transfer of data in remote patient monitoring devices are regulated in MOH procedures** which outline the requirements for access to medical data and for processing it. The Privacy regulations provide guidance as to security data measurements required for collecting and storing medical data and particular requirements when exporting data abroad. Due to the **"adequacy decision" of the European Commission, personal data from the EU can be transferred to Israel without any need for additional measures**. Special legal protection may apply to certain categories of data, such as biometric data, genetic data and psychiatric data.

The **collection of data through medical research requires regulatory approval** in accordance with the Public Health Regulations (Medical Researches Involving Humans), and MOH procedures. Generally, the MOH's procedures adopt and follow international guidelines with respect to medical research. Secondary use of data could be approved by the Helsinki Committee (the IRB) for future research-use under certain conditions.

Who Owns the Medical Data?

This is a worthy question for which there is no unequivocal legal answer. **Israeli legislation refers to the patients' rights**, such as the right to privacy of one's medical data and the right to receive a copy of the data (The **Privacy Protection Law** and the **Patient's Rights Act**). The **digital medical data-base belongs to the medical institution**, which is also responsible, regulatory-wise, for protection of the stored data therein.

Medical Data Accessibility – Current Status

Currently there is **no overall – national regulatory – based solution for sharing medical data for primary use** – for the purpose of receiving or providing healthcare services. **Many HMOs and hospitals enable patient to access their medical data digitally**. In addition, the **MOH initiated a platform** which **enables the transfer of certain medical data between hospitals and HMOs for primary use**, i.e., the purpose of treatment. The medical data can be viewed by the receiving physician but cannot be stored. **Patients are not asked to provide prior consent** (**according to the Patients' Rights Act which allows the transfer of data between care providers for primary use**). This **platform is voluntary**, and not all hospitals and service providers have joined it.

Companies and researchers can only access medical institution's health data in a regulatory-approved medical research, and according to the protocol and the informed consent form (unless waived by the IRB), and **subject to the privacy legislation's limitations**. Future use of these data is also subject to the same regulatory conditions. Companies often collect data directly from users via applications and subject to their consent, usually manifested in privacy policy.

The Draft Medical Information Portability Law

Recently, the Ministry of Health published the draft Medical Information Portability Law ("Bill") and asked for comments by the public. The main purpose of the Bill is to enable patients to receive and share health information with healthcare providers digitally and in a unified format.

Under the Bill, hospitals, HMOs, clinics and providers will be obligated to accommodate patient requests to transfer medical data to authorized recipients ("Data Recipients"). To qualify as a Data Recipient under the Bill, the relevant entity will be required to obtain and maintain a license from a commissioner to be appointed by the Ministry of Health. The Bill **enables companies** – and not only medical institutions – **to act as data recipients** and receive health data, **subject to receiving a license from the commissioner and authorization by the patient**. Furthermore, the Bill sets data standardization requirements to enable sharing of medical data.

Health data may be used only for the provision of the health service appearing in the license, and such use is subject to patient consent. Health data may also be used for statistical purposes to improve health services on the condition that the products of such use do not contain identifiable personal data. **Use of health data for marketing and advertising purposes, including marketing medical services, is prohibited**.

Medical research will **continue to be conducted pursuant to existing laws and in accordance with Helsinki Committee requirements, patient consent requirements, and existing regulations**. Medical institutions may enable external researchers to access data within the institution's secured information platform even when such researchers do not hold a license.

Although the **Bill is an important step in establishing health data accessibility**, it raises several **challenges**: the **technological and administrative requirements are quite burdensome, especially considering small service providers – clinics, and startups**; There is **no legal arrangement for secondary use of data** other than in the framework of medical research, so that, secondary use for the purpose of improving an algorithm for future development may not be possible; the **requirement for obtaining government approval prior to engaging in certain change of control transactions** also raises difficulties. The **prohibition against receiving consideration in connection with data transfers also raised some objections**. As public comments are submitted and discussed, one can still expect some changes to be introduced in the Bill.[8]

Conclusion and Outlook

Both Germany and Israel are working at full speed on adapted legislation for the primary and secondary use of health data and maintain regular exchanges on this.

In addition to a large number of relevant stakeholders in the health and care system, **patients and industry are being involved in the process in order to design a binding framework that will benefit all stakeholders**. This development is worthy of support and has also been increasingly expressed during the GIHF-AI discussion rounds to date. **Especially also with regard to the use of health data for AI-based systems**, as AI relies on high-quality health data.

Europe currently has a unique opportunity to become a pioneer in trustworthy AI. In order not to miss this opportunity and play into the hands of states where health data is not handled as carefully as in Europe, it is important to design the regulatory framework with care. **Close integration of the GDNG and the EHDS is essential** to reduce legal uncertainties and difficulties in interpreting the regulations. At the same time, it is worth **taking a look at countries such as Israel, where digitized, innovative healthcare is part of everyday life** and similar legal frameworks apply as in Europe.[9]

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